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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,552	08/02/2001	Hideakira Yokoyama	0020-4883P	4627

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EXAMINER

JAGOE, DONNA A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/890,552

Applicant(s)

YOKOYAMA ET AL.

Examiner

Donna A. Jagoe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 27, 2002 has been entered.

***Claims 1-8 and 11-17 are pending in this application.***

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Ikeda Mohandou K.K. Japanese 62-592019 (A) dated 14 March 1987 (cited in IDS of paper number 5).

The claims are drawn to a composition and methods of use of an external preparation consisting essentially <sup>of</sup> active ingredients consisting of l-menthol and one or more essential oils and a pharmaceutical base such as an ointment and patch.

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Ikeda Mohandou K.K. teach l-menthol, along with nutmeg oil and fennel oil as active constituents in a composition for *inter alia* analgesic use. It further teaches that the l-menthol has improved analgesic and refreshing action. The composition is in the form of an ointment, cream, gel, solution, caaplasma and adhesive application agent (patch). The composition contains preferably 0.2% to 5% essential oils and 2% to 10% l-menthol.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-5, 7-8 and 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda Mohandou K.K. Japanese 62-592019 (A) dated 14 March 1987 (cited in IDS of paper number 5).

The claims are drawn to a composition and methods of use of an external preparation consisting essentially active ingredients consisting of l-menthol and one or more essential oils and a pharmaceutical base such as an ointment and patch and method of use for relief of migraine pain.

Ikeda Mohandou K.K. teach l-menthol, along with nutmeg oil and fennel oil as active constituents in a composition for *inter alia* analgesic use. It further teaches that the l-menthol has improved analgesic and refreshing action. The composition is in the form of an ointment, cream, gel, solution, caaplasma and adhesive application agent (patch). The composition contains preferably 0.2% to 5% essential oils and 2% to 10% l-menthol.

1. It differs in that it does not teach the specific essential oils of the instant application. The criticality of rose oil and lavender oil in the instant application has not been demonstrated. Therefore it would have been obvious to substitute nutmeg oil, fennel oil, eucalyptus oil and turpentine oil for rose oil, juniper oil, peppermint oil, juniper oil and rosemary oil. One would have been motivated to choose the above substitution because the purpose of the essential oils is to cover the unsavory odor of the l-menthol.

2. It does not teach specifically for the relief of migraines. It does however teach the composition to be useful as an analgesic. Since analgesics are used to relieve migraine pain, one would have been motivated to try the above cited composition to

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relieve migraine pain even though it is not specifically stated as such motivated my the recitation of Ikeda Mohandou K.K. that the composition is useful as an analgesic preparation.

3. It does not specifically teach the hydrophilic high molecular weight substances and polyhydric alcohol of the instant application. However, Ikeda Mohandou K.K. does teach that the composition can be used in an ointment base in which these agents are known to be used as well as in a formulation called an adhesive application, or otherwise known as a patch.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna A. Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

dj  
December 1, 2002

12/01/02 13:00  
PRIMARY EXAMINER  
GROSS & CO  
*[Signature]*